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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/697,599 | 10/29/2003 | Austin L. Gurney | 39766-0125A | 7558 |

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| EXAMINER | |
|---|---|
| HISSONG, BRUCE D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/697,599 | GURNEY, AUSTIN L. | |
| | Examiner | Art Unit | |
| | BRUCE D. HISSONG | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *30 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-16 and 18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/2/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/2/2007 and 10/30/2007 has been entered.

2. Claims 14-16 and 18-28 are pending and are the subject of this office action.

***Information Disclosure Statement***

The information disclosure statement received on 8/2/2007 has been considered by the Examiner.

***Claim Objections***

Objection to claim 14, as set forth on page 2 of the office action mailed on 5/29/2007, is withdrawn in response to Applicant's amendments to the claim to recite "a mammalian subject having been determined to express".

***Claim Rejections - 35 USC § 112, first paragraph – enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 14-16 and 18-28 under 35 USC § 112, first paragraph, regarding lack of enablement for methods of treating all possible diseases characterized by increased IL-17, as set forth on pages 4-5 of the prior office action mailed on 3/14/2006 and pages 3-4 of the office action mailed on 5/29/2007, is *withdrawn* in response to Applicant's arguments that the specification teaches inhibition of

IL-17 production by inhibition of IL-23, and that a person of ordinary skill in the art would correlate these *in vitro* data to *in vivo* methods of treatment.

These arguments have been fully considered and are persuasive in light of the teachings of Bowman *et al* and Zhang *et al*, which suggest the use of IL-23 antagonists for treatment of inflammatory disease.

***Claim Rejections - 35 USC § 112, first paragraph – written description***

Claims 14-16 and 18-28 *remain rejected* under 35 USC § 112, first paragraph, regarding recitation of a claim limitation which was deemed to represent new matter, as set forth on page 5 of the office action mailed on 5/29/2007.

Specifically, the phrase "determined to express an elevated level of IL-17" was not found to be expressly asserted in, or flow naturally from, the instant specification as originally filed. In the response received on 8/2/2007, the Applicant argues that the originally filed specification discloses methods and pharmaceutical compositions for treatment of inflammatory diseases characterized by elevated expression of IL-17, and such diseases along with literature references discussing determination of IL-17 levels are disclosed. Because these diseases are characterized by elevated expression of IL-17, it follows that determination of the IL-17 level needs to precede administration of an anti-IL23 antibody. Therefore, the Applicant submits that the newly added limitation does flow naturally from the specification as originally filed.

These arguments have been fully considered and are not persuasive. As written, the amended claims can be interpreted as on a method comprising a method step of measurement of IL-17 levels in a patient and comparison to a healthy individual, wherein this method step must precede the administration of an IL-23 antagonist. Although the Applicant has amended the specification to include specific passages from literature incorporated by reference (specifically the teachings of Kotake *et al*, Wong *et al*, and Matusevicius *et al* as they relate measurement of IL-17 levels in patients), these teachings reflect measurements of IL-17 in various diseases, and thus provide examples of diseases which are characterized by increased IL-17 levels, and methods for determining IL-17 levels. However, the incorporation of a specific method step comprising determination of IL-17 levels and comparison to healthy individuals, wherein this method step must precede administration of anti-IL-23 or anti-IL-23R antibodies, does not appear to have been contemplated by the originally filed specification. It is known in the art that inflammatory disease can be characterized by the presence of multiple cytokines. For

example, Wong *et al* (cited in the Applicant's response received on 10/30/2007), shows that several cytokines are elevated in systemic lupus erythematosus. Although IL-17 is taught to be one of these cytokines, there is nothing in this disclosure that would point specifically to determination of IL-17 levels as a necessary, preliminary step of any treatment method. Thus, while the incorporated passages show that IL-17 levels can be determined, the recitation of such teachings is not sufficient to provide adequate description showing that this specific method step was contemplated and intended at the time the application was originally filed.

***Conclusion***

No claim is allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong
Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647